IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Ryuji UENO

Application. No.: 10/567,462 Group Art Unit: 1105
Confirmation No.: 1105 Examiner: Kendra D. Carter
Filed: February 5, 2007

For: COMPOSITION AND METHOD FOR PROMOTING HAIR GROWTH

DECLARATION UNDER RULE 1.132

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, TABUCHI, Reiko, a citizen of Japan and residing in Kawanishi-shi, Hyogo, Japan declare and say as follows:

1. I graduated from Department of Pharmacy, School of Pharmaceutical Science, Mukogawa Women's University, Hyogo Japan in March 1981 and hold a bachelor's degree in pharmacology.

2. From April 1981 to March 2003, I was an employee of UENO FINE CHEMICALS INDUSTRY, LTD of Osaka, Japan and engaged in the research and development in the field of pharmacology and toxicology. Since April 2003 up to this time, I have been an employee of R-TECH UENO, LTD of Tokyo, Japan.

3. At present, I am a member of The Japanese Society of Toxicology.

4. I am familiar with the subject matter of the above-identified application.

5. I have read the Office Action mailed December 11, 2009 and the references cited therein and am familiar with the

subject matter thereof.

6. In order to show that the invention claimed in the above-identified application is unobvious over Johnstone (US6,262,105) in view of Skuballa et al. (US 4,088,775), the following experiments have been done.

EXPERIMENTS

i. Animals:

Japanese White rabbits [Std: JW/CSK] 10 weeks old, male n=5

ii. Test substances:

[PG Compound A] 0.12% PG Compound A (13,14-dihydro-15,15-ethylenedioxy-20-ethyl-PGF2α ethyl ester) in the vehicle for Rescula®

[Rescula®] 0.12% isopropyl unoprostone

[Vehicle] The vehicle for Rescula®

[Saline] Physiological saline (Otsuka Pharmaceutical Factory, Inc., Tokyo, Japan)

iii. Administration protocol:

Thirty five micro liter (35µl) of each test substance was administered once to one eye of a rabbit with Pipetman® and the same volume of the vehicle or saline was administered to the other eye of the same rabbit.

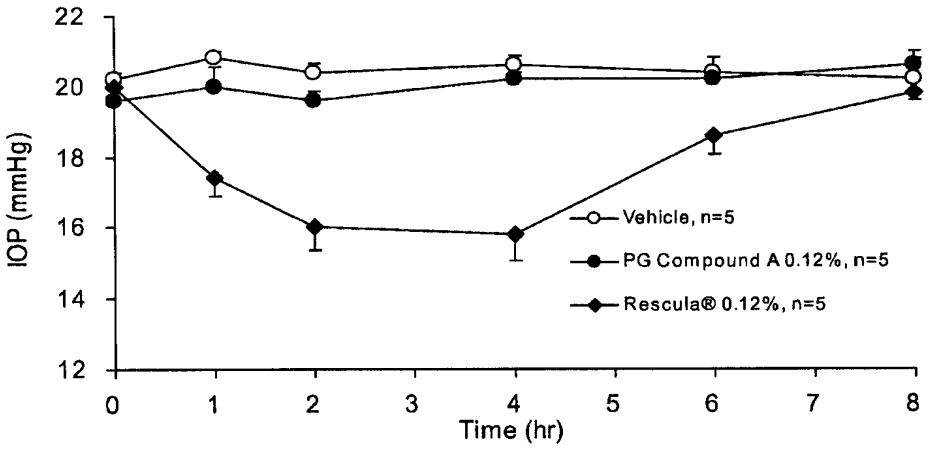
iv. Test Groups:

one eye	the other eye	volume	n
Control	Saline	35 µL/eye	5
PG Compound A	Vehicle	35 µL/eye	5
Rescula®	Vehicle	35 µL/eye	5

v. Measurement of Intraocular Pressure

Rabbits were fixed on braces and the eyes were locally anesthetized with 0.4% oxybuprocaine hydrochloride ophthalmic solution (Benoxil®, 0.4%). Intraocular pressure of the rabbits was measured using a tonometer (Model 30 Classic™, Mentor O & O Inc., USA). Intraocular pressure of the rabbit was determined before (0 hour) and 1, 2, 4, 6 and 8 hours after the administration of the test substances.

vi. Results:



As is shown in the graph, 13,14-dihydro-15,15-ethylenedioxy-20-PGF2α (PG compound A) does not have the effect to lower the IOP.

7. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Dated this day of Mar. 16, 2010

R. Tabuchi

Reiko TABUCHI